User's Manual

Prodigy

Blood Glucose Monitoring System

100 mg/dL

9-27
6:30 AM
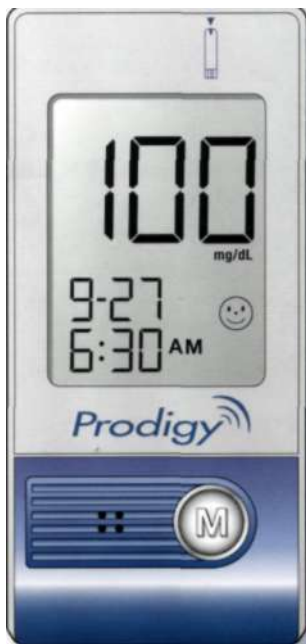
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DDI

Diagnostic Devices, Inc.

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Dear Prodigy System Owner:

You have chosen one of the best blood glucose monitoring systems available. This booklet has important information about the system. Please read it carefully.

Your system provides you with accurate, plasma-calibrated test results. This feature makes it easy for you and your doctor to compare your meter results with laboratory results.

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that keeping blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%.* The results you get with the system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

A warranty registration card is included with your system. Please complete it and mail it to us.

* American Diabetes Association position statement on the Diabetes Control and Complications Trial (1993).

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The system is intended for use outside the body (in vitro diagnostic use). It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples. The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or for the testing of newborns.

CAUTION:

Before using any product to test your blood sugar (blood glucose), read all instructions and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional. These recommendations apply to all blood glucose monitoring systems and are supported by the Diabetes Educator Section of the Canadian Diabetes Association.

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Important Information

• Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.

• Test results below 60 mg/dL (3.3 mmol/L) mean low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L) mean high blood glucose (hyperglycemia). If you get results below 60 mg/dL or above 240 mg/dL, and do not have symptoms, first repeat the test. If you have symptoms or continue to get results that fall below 60 mg/dL or above 240 mg/dL, follow the treatment advice of your healthcare professional.

• If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all instructions described in the Prodigy owner's booklet, call your healthcare professional.

• A red blood cell count (hematocrit) that is very high (above 60%) or very low (below 20%) can cause false results.

• Elevated blood triglyceride, reducing substances such as uric acid and ascorbic acid at normal blood concentration, or acetaminophen, dopa, methyldopa, L-dopa, and tolbutamide at normal blood concentrations do not significantly affect the test results.

• This system maybe used at altitudes up to 10,742 feet (3275m) without an effect on test results.

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GETTING STARTED
**The Prodigy Diabetes Blood Glucose Test System**

The Prodigy system consists of three main products: the Prodigy blood glucose meter, Prodigy test strips, and Prodigy control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only Prodigy test strips and Prodigy control solutions with the blood glucose meter.

CAUTION:

Check your system to be sure the outer carton seal is not missing or broken. If either of these conditions occurred, please return your system to the place of purchase.

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Prodigy Blood Glucose Meter
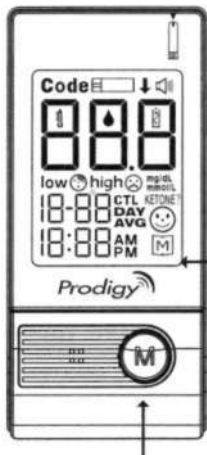
-TEST SLOT
The test slots is where you insert the test strip for testing. The meter will turn on automatically when you insert a test strip.

-SET BUTTON
The Set button (in the back of the meter) is used to set the date, time, units and other meter functions.

-DISPLAY
Your test results are displayed here. The display guides you through the **test** using symbols and simple messages.

MAIN BUTTON
The main button in front of the meter is used to set up the meter, enter the memory mode, change the value of date and time, unit setting, memory deleting and to turn the meter on and off.
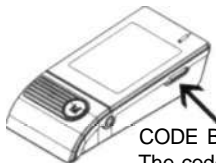
CODE BUTTON
The code button at the side is used to CODE the meter to the strip.

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Meter Display Segments

TEST STRIP SYMBOL
Flashes when you turn the meter on. The symbol stays on when the strip has been inserted.

BLOOD DROP SYMBOL
Appears when the meter is ready for you to add blood to strip.

CODE
Displayed with the code number currently in the meter.

TEMPERATURE SYMBOL
Appears with ambient temperature.

LOW SYMBOL
Appears when test result is lower than normal.

DATE & TIME

HIGH SYMBOL
Appears when test result is higher than normal.

CTL SYMBOL
Appears when in control solution test. Its result won't be stored in the memory.

VOICE ON/OFF
Indicates voice on/off. (Only for meter model No. 51720)

TEST RESULT AREA
Test results are displayed here. (A decimal point appears when the unit of measurement is millimoles per litre.)

LOW BATTERY SYMBOL
Appears when it is time to change the batteries.

UNITS OF MEASUREMENT
Depending upon how the meter is set, either mmol/L or mg/dL will appear with the test result.

KETONE WARNING
When your blood glucose test result is above 13.3mmol/L (240mg/dL), this symbol will appear with "?" sign on the display.

HAPPY FACE
Appears when test result is normal.

MEMORY SYMBOL
Indicates a test result store in memory.

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Prodigy Test Strips

Your system measures the amount of sugar (glucose) in whole blood. Blood is applied to the absorbent hole of the test strip and is automatically drawn into the reaction cell where the reaction takes place.

The test strip consists of the following parts:

CONTACT BARS
Insert this end of the test strip into the meter. Push it in firmly until it will go no further.

TEST STRIP HANDLE
Hold this part to insert the test strip into the slot.

CONFIRMATION WINDOW
This is where you confirm if enough blood has been applied to the absorbent channel of the strip.

ABSORBENT CHANNEL
Apply a drop of blood here, the blood will be drawn automatically.

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Important Test Strip Information

- Store test strip packages in a cool, dry place below 104°F (40°C). Keep **away** from direct sunlight and heat.
- Store your test strips in their original vial only.
- After removing a test strip from the vial, immediately replace the vial cap **and** close it tightly.

- With clean, dry hands, you may touch the test strip anywhere on its sur face when removing it from the vial or inserting it into the meter.

- Use each test strip immediately after removing it from the vial.

- Write the discard date on the vial label when you first open it. Discard remaining test strips 90 days after first opening date.

- Apply only blood sample or control solution to the absorbent hole. Applying other substances to the absorbent hole will cause inaccurate **results.**

- Do not use test strips beyond the expiration date printed on the package since they may cause inaccurate results.

- Do not bend, cut, or alter a test strip in any way.

CAUTION:

Keep the test strips away from children; the strips can be a potential choking hazard. Never chew or swallow a test strip.

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BEFORE TESTING

Checking the Display

Each time you insert a test strip into the
meter to turn the meter on , the meter
will display "CH" with the strip symbol
briefly. This tells you that the system is
performing several self-checks.

For meter model No. 51720, you will hear a
voice message, "the code number is (number).'

Coding the Meter

The Code Button is used to calibrate the
test strips with the meter for accurate results.
Please code the meter before using it
for the first time and then every time you
change to another vial of test strips.
Each time you test, check that the code
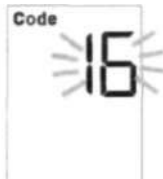number on the meter display matches
the code number on the test strip vial.
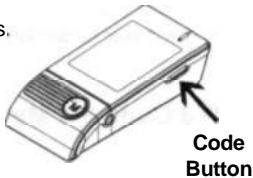
**Code
Button**

CAUTION:

*If the code number displayed on the meter
does not match the number printed on the vial,
test results may be inaccurate .*

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STEP 1 Enter the Code Mode

Start with the meter turned off. Press the Code Button. The Code symbol and "SEL" will appear on the LCD display, followed by the code number, with the number blinking.

STEP 2 Match the Code Numbers

Compare the code number flashing on the LCD display with the code number on the test strip vial. If the two code numbers match, you may begin testing. If they do not match, follow Step 3. When you first use the meter, you need to code the meter before testing.
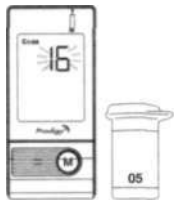
STEP 3 Code the Meter

Press and release the Code Button to advance one number. When the code you need appears on the display, press the Main Button to set the code and turn off the meter.
If you do not press any button in two minutes, the meter will turn off automatically..

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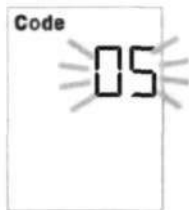
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Checking the System with Prodigy Control Solution

Prodigy control solutions are used to check that the meter and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results.

Prodigy control solutions contain a known amount of glucose that reacts with test strips. The Low and High level Control solutions are intended to check the monitoring system in different measurement ranges. Compare your control solution test results with the expected range printed on the test strip vial label.

Control solution should be used to :

* Practice the test procedure
* Make sure your meter and test strips are working together properly
* Ensure you are performing the test correctly

Before you use the meter to test your blood for the first time, practice the procedure using control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.

Do a control solution test:

* When you begin using a new vial of test strips
* At least once a week
* Whenever you suspect that the meter or test strips are not working properly
* When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate
* If you drop the meter
* After you change the meter batteries

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Important Control Solution Test Information

- Use only Prodigy control solutions.
- Check the expiration date on the control solution vial. Do not use if expired.
- Control solution, meter, and test strips should come to room temperature (68-77°F / 20-25°C) before testing.
- Shake the vial, discard the first drop of control solution, and wipe off the dispenser tip to ensure a good sample and an accurate result.
- Use only for 90 days after first opening. Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days .
- Store the control solution tightly closed at temperatures below 86°F (30°C). Do not refrigerate.

CAUTION:

The control solution range printed on the test strip vial is for Prodigy control solution only. It is used to test meter and test strip performance. It is not the recommended range for your blood glucose level.

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How to do a control solution test:

STEP 1 Insert Test Strip

Insert a test strip with contact bars end first and facing up, into the test port. (Contact bars must be inserted all the way into the meter or you may get an inaccurate test result.) The meter will turn on automatically. "CH" and strip symbol will appear briefly on the display. Then the ambient temperature is displayed, followed by the ● symbol with the code number. Be sure the code number on the display matches the code number on the test strip vial. If the code numbers do not match, code the meter correctly.

After the symbol appears on display, press the Main Button; "CTL" will appear on the display. With the "CTL" sign on the display, the meter will not store your test result in memory. If you decide not to perform a control solution test, the "CTL" sign will disappear when you press the Main Button again.

CAUTION:

Every time you perform a control solution test, you must enter into the "CTL" test mode so that the test will not be stored in the meter memory.

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STEP 2 Apply Control Solution

Shake the control solution vial well. Remove the cap. Squeeze the vial, discard the first drop, and wipe off the dispenser tip to ensure an accurate result. Squeeze the vial again to get another drop and place the drop on your finger tip first. Then, apply the drop to the absorbent hole of the test strip (where it meets the narrow channel) until the drop is drawn into the test strip, the confirmation window is filled, and the meter begins to count down.

CAUTION:

To avoid contaminating the control solution with the content of the test strip, you have to place a drop of control solution on a clean surface or on your finger tip first. Then touch the test strip to the drop.

correct

incorrect

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STEP 3 Result Appears in 6 Seconds.

The meter will count down and the control solution test result will appear. Compare the result with the range printed on the test strip vial . The result should fall within this range.

For meter model No. 51720 you will hear a voice message, "the blood glucose is (number) (unit)".

Comparing control solution results

If test results fall outside the range printed on the test strip vial, repeat the test. Out-of-range results may be caused by one or more of the following:

- Error in performing the test
- Failure to shake the control solution vial vigorously
- Expired or contaminated control solution
- Control solution that is too warm or too cold
- Failure to discard the first drop of control solution and wipe the dispenser tip clean
- Improper coding of the meter
- Test strip deterioration
- Meter malfunction

CAUTION:

If you continue to get control solution test results that fall outside of the range printed on the vial, the system may not be working properly. Do not use the system to test your blood if you continue to get test results that fall outside of the range. If you are unable to resolve the problem, call the Technical Support Line at 1-800-243-2636.

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TESTING YOUR BLOOD

Be sure to read this section and the test strip package insert found in the test strip box carefully before testing. Make sure you have all items needed to test:

A. Blood Glucose Meter
B. Test Strip
C. Lancing Device
D. Sterile Lancet

Step-by-Step Test Procedure

STEP 1 Insert the test strip
Insert the test strip with contact bars end first and facing up into the test port fully. The bars must be all the way into the meter to avoid an inaccurate result. The meter will turn on automatically. "CH" and strip symbol will appear briefly on this display. Next, the ambient temperature will appear and followed by the symbol with the code number. Code the meter if necessary.

For meter model No. 51720 you will hear a voice message: "please apply blood into the strip".

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STEP 2 Apply Sample

Obtain a rounded drop of blood using a Lancing Device. The blood sample must be at least 0.6 microliter in volume (○actual size) or you may get an inaccurate test result. When the "🌢" symbol appears on the display, apply the drop of blood to the absorbent hole of the test strip. Do not push your finger against the test strip or try to apply a smeared sample.

The blood should completely fill the confirmation window before the meter begins to count down. If the confirmation window does not fill completely before the meter begins to count down, do not add more blood to the test strip; discard the test strip and retest. If you have trouble filling the test strip, contact the technical support line.

NOTE: If you do not apply a blood sample within 3 minutes, the meter will turn itself off. You must remove the test strip and insert it back into the meter to restart the test procedure.

STEP 3 Accurate Results in 6 Seconds

Your blood glucose test result will appear after the meter counts down. Blood glucose test results are automatically stored in the meter memory. Turn the meter off by removing the test strip. Discard the used test strip carefully to avoid contamination.

For meter model No. 51720 you will hear a voice message, "the blood glucose is (number) (unit)".

Plasma calibrated result (example)

The Prodigy meter provides accurate, plasma-calibrated test results that can be compared directly with laboratory results.

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Special Messages

Some special symbols or messages will appear depending on your test result.

1) When below 20 mg/dL (1.1 mmol/L), "Lo" will appear on the meter display instead of numbers.

2) When between 20 to 70 mg/dL (1.1 and 3.9 mmol/L), the "low" symbol will appear with your test result.
Lo or "low" symbol indicates hypoglycemia (low blood glucose.) You should immediately treat hypoglycemia as recommended by your healthcare professional.

3) When within optimal range, which means 70 to 120 mg/dL (3.9 to 6.6 mmol/L), a smile will appear with your test result.

4) When between 120 to 240 mg/dL (6.6 and 13.3 mmol/L), the "high" symbol will appear with your test result.

5) When above 240 mg/dL (13.3 mmol/L), "KETONE?" symbol will appear on the meter display. This indicates there is a possibility of Ketone accumulation if you are type 1 diabetic. Please seek immediate medical assistance.

6) When above 600 mg/dL (33.3 mmol/L), "Hi" will appear on the meter display instead of number. This indicates severe hyperglycemia. Please seek immediate medical assistance.

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USING THE METER MEMORY

Your Meter stores the 450 most recent blood glucose test results with date and time in its memory. It also provides you with 7,14,21,28,60 and 90 day averages of your blood glucose test results. You can review the test results in memory with these easy steps.

STEP 1 Enter the Memory Mode

With the meter turned off, press the main button twice. The 7 day average will appear, indicating that you are in the memory mode. If you continue to press The Main Button, the 14, 21, 28, 60 and 90 day average will appear. You can then review the last 450 tests in the memory.

The 7 day average is calculated from the blood glucose results obtained during the last 7 days. It also indicates how many blood glucose tests have been performed within this period, e.g., 58 (58 tests in the last 7 days).

When using the meter for the first time,
"—" will appear, showing that
there are no test results in memory.

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The 14-day average is calculated from the blood glucose results obtained during the last 14 days. It, too, indicates how many blood glucose tests have been performed, e.g., 24 (24 tests in the last 14 days). When using the meter for the first time, "14 DAYa—" will appear, showing that there are no test results in memory . It's all the same to the 21, 28, 60 and 90 day average.

STEP 2 Recall Test Results
After the 90-day average, the most recent test result with date and time will be shown. Press the Main Button once and the next most recent test result will appear. Each time you press and release the main button, the meter will recall up to your last 450 test results in order. When the memory is full, the oldest result is dropped as the newest is added.

When reaching the last set of result, "End" will be shown on LCD display, and the meter turns off automatically.

NOTE: If no button is pressed for 2 minutes, the meter will show "OFF" and turn off automatically.

STEP 3 Exit The Memory Mode
Press the Main Button for three seconds to turn off the meter.

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COMPARING METER
AND LABORATORY RESULTS

Test results from meter and laboratory are both expressed in plasma-equivalent units. However, the result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way. (See test strip package insert for typical accuracy and precision data, and for important information on limitations.) To make an accurate comparison between meter and laboratory results, follow the guidelines below.

Before you go to the lab:

- Perform a control solution test to make sure that the meter is working properly
- It is best to fast for at least eight hours before doing comparison tests
- Take your meter with you to the lab

While at the lab:

- Make sure that the samples for both tests (the meter test and the lab test) are taken and tested within 15 minutes of each other

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- Wash your hands before obtaining a blood sample
- Never use your meter with blood that has been collected in a gray-top test tube
- Use fresh capillary blood only

You may still have a variation from the result because blood glucose levels can change significantly over short periods, especially if you have recently eaten, exercised, taken medication, or experienced stress. In addition, if you have eaten recently, the blood glucose level from a finger stick can be up to 70 mg/dL (3.9 mmol/L) higher than blood drawn from a vein (venous sample) used for a lab tesf.

Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (severe dehydration) may also cause a meter result to be different from a laboratory result.

References

1. Surwit, R.S., and Feinglos, M.N.:
   Diabetes Forecast (1988), April, 49-51.
2. Sacks, D.B.: "Carbohydrates." Burtis,
   C.A., and Ashwood, E.R.(ed.), Tietz
   Textbook of Clinical Chemistry.
   Philadelphia: W.B. Saunders Company (1994),959.

SETTING THE METER AND DELETING THE MEMORY

Before you start using the meter for first time you may need to setup the time, date, unit of measurement and unit of temperature and language. You also may need to enter the set mode and reset the meter if you need to change the time or if you remove the batteries.

Setting the Time, Date, Unit of Measurement
Unit of Temperature and Memory Deletion

To set the time, you must first enter the setting mode. Start with the meter off. Then press the Set Button located in the batteries compartment. The meter is now in the set mode.

STEP 1. Set the Year
First, all symbols on LCD will be displayed. Then the year will appear, with the number flashing. Press and release the Main Button to advance one year. To move faster, hold the Main Button down. With the correct year on the display, press the Set Button and the date will appear on the display with the month segment flashing.

STEP 2. Set the Month
Press and release the Main Button until the correct month appears. To move faster, hold the Main Button down. With the correct month on the display, press the setting button and the day segment will start flashing.

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STEP 3 Set the Day
Press and release the Main Button until the correct day appears. To move faster, hold the Main Button down. With the correct day on the display, press the Set Button and the time will appear on the display with the hour segment flashing.

"Before setting the time, you must have first set the date.

STEP 4 Set the Hour
Press and release the Main Button to advance one hour. To move faster, hold the Main Button down. With the correct hour on the display, press the Set Button and the minutes segment will start flashing.

STEP 5. Set the Minutes
Press and release the Main Button to advance one minute. To move faster, hold the Main Button down. With the correct minute on the display, press the Set Button and the current unit of measurement will start flashing.

NOTE: Your meter displays 7, 14, 21, 28, 60 and 90 day averages which you can access from the meter memory. These averages are calculated from results obtained during the 7, 14, 21, 28, 60 and 90 days preceding the current date and time settings. When the date and time are changed, the 7, 14, 21, 28, 60 and 90 day averages may change.

Your meter can display test results in milligrams per deciliter (mg/dL) or millimoles per litre (mmol/L). The mg/dL unit is standard in the United States. The mmol/L unit is standard in Canada.

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STEP 6. Select mg/dL or mmol/L.
Press and release the Main Button until the
unit of measurement you are choosing
appears on the display. Press the Set
Button and the current unit of temperature
will start flashing.

STEP 7. Select °C or °F
Press and release the Main Button until the unit of
temperature you are choosing appears on the display.
Press the Set Button and the meter will display "dEL"
with flashing "mem" symbol.

STEP 8. Delete memory and exit the setting mode
"dEL" and flashing M symbol appears on the
display. When you press the Main Button, "dEL'
will flash too. Press the Main Button again to
delete all the meter Memory records. When the
meter displays the smile,it means that the mem-
ory is deleted. You can press the Set Button to
turn off the meter. If you do not want to delete
the memory, do not press the Main Button, but
press the Set Button again to turn off the meter.

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DOWNLOADING TEST RESULTS
TO YOUR COMPUTER

Prodigy allows you to download all your test results in your computer helping you or your health care professional track changes in your blood glucose level over time. To start downloading your results you need to connect the downloading cable* to your computer and to the Prodigy meter Download Port, and install a free software to your PC that will let you complete this process easily. You can get the free copy of this software on our web-site at: www.diagnosticdevicesinc.com 'Downloading cable sold separately.

CARING FOR YOUR METER

Maintenance

Your meter does not require special maintenance. As no blood or control solution comes in contact with the meter, there is no special cleaning required. Take care to avoid getting dirt, dust, blood, control solution or water inside the meter through the test port or data port. Store the meter in its carrying bag after each use. A cloth dampened with water and mild detergent can be used to wipe down the outside of the meter. Your meter is a precision instrument. Please handle it with care.

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Power

Your Prodigy Blood Glucose monitoring system uses two (2) AAA 1.5.V alkaline batteries (included with your system) that need to be installed in the meter before use. The new batteries will provide you with enough power to perform about 3,000 tests. When replacing the batteries, use only (2) AAA 1.5.V alkaline batteries.

The meter will alert you when the power is getting low by displaying two different messages:

1. The symbol I appears on the display when the meter is turned on and all other display messages are functional. From the time the symbol first appears, there is enough power left for about 50 tests. The test results will be accurate, but it is time to change the batteries.

2. The symbol I appears with the E-b symbol on the displays by itself. This means that the batteries will not provide enough power for a test. You must change the batteries.

Replacing the batteries

a. Make sure that the meter is turned off.
b. Turn the meter over and locate the battery compartment.
c. Press the buckle on battery cover and lift up to remove cover.
d. Remove the old batteries. Insert two (2) AAA 1.5.V alkaline batteries, making sure you follow the batteries diagram for a proper installation.
e. Replace battery cover back into place.

NOTE: Replacing the batteries does not affect the meter's memory (previous test results stored in memory). However, the time and date settings may need to be updated.

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DISPLAY MESSAGES AND PROBLEM-SOLVING GUIDE

Following is a summary of some display messages and symbols. These messages help to identify certain problems but do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error message or a symbol. In the event of a problem, refer to the information under action.

Message	What it means	Action
1.) E-b	The symbol ▯ appears with this message on the display by itself. This means that the batteries will not provide enough power for a test.	Replace the batteries at once.
2.) E-U	Error message could be caused by a used test strip, or a temporary or permanent electronics problem occurred.	Repeat the test with a new test strip. If the error message appears again, please call the Technical Support Line at 1-800-243-2636.
3.) E-t	The temperature of the environment, meter, or test strip was below or above the system operation range. You can not perform a test until the meter and test strip reach a temperature within the operation range of 50~104°F (10~40°C).	Repeat the test after the meter and test strip have reached a temperature within the operation range.
4.) E-E	Error message indicates that there is a problem with the meter.	Review the instructions and try again with a new test strip. If the problem persists, please call the Technical Support Line at 1-800-243-2636.

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Message	What it means	Action
5.)E-O	Error message indicates that there may by a problem with the meter.	Repeat the test with a new test strip. If the problem persists, please call the Technical Support Line at 1-800-243-2636.
6.)E-F	Error massage indicates that you may have removed the strip after applying blood to the absorbent channel.	Review the instructions and try again with a new test strip.
7.)E-A	Error message indicates that there is a problem with the meter.	Review the instructions and try again with a new test strip. If the problem persists, please call the Technical Support Line at 1-800-243-2636.

If the meter does not display a message after inserting a test strip:

PROBABLE CAUSE	WHAT TO DO
a. Batteries exhausted.	Replace the batteries.
b. Batteries incorrectly installed or absent	Check that the batteries are correctly installed following the diagram.
c. Test strip inserted upside down or incompletely	Insert the test strip correctly with the contact bars end first and facing up.

If the test does not start after applying the sample:

a. Insufficient blood sample	Repeat the test with a new test strip and larger sample.
b. Defective test strip	Repeat the test with a new test strip.
c. Sample applied after automatic shutoff (two minutes after last user action)	Repeat the test with a new test strip; apply sample only when " ● " appears on the display.
d. Defective meter	Please call the Technical Support Line at 1-800-243-2636.

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SPECIFICATIONS

Dimension: 41.6mm x 82.3mm x 21.4mm
Power source: two (2) AAA 1,5V alkaline batteries
Battery life: Over 3,000 determinants
Display: Large LCD
Memory : 450 measurement results with date and time
Auto electrode inserting detection
Auto sample loading detection
Auto reaction time count-down
Sleeping mode: Power consumption less than 20uA
Auto turn-off after 3 minutes without action
Temperature warning
Operating condition: 50°F-104°F (10°C ~40°C)
Operating humidity range: 10-90% R.H. (non-condensing)
Storage/Transportation condition: -4°F~158°F (-20°C ~70°C), 5%~95% R.H.
Measurement Units: Either mg/dL or mmol/L
Measurement Range: 20-600mg/dL (1.1~33.3mmol/L)

Performance characteristics
- **Accuracy:** Whole blood glucose test results were compared with YSI-2300 glucose analyzers. 100% were with 15 mg/dL (0.83 mmol/L) at concentration < 75 mg/dL (4.2 mmol/L) and 100% with glucose concentration < 75 mg/dL (4.2 mmol/L) were with ±20% of the reference values. The study shows that the Prodigy glucose monitoring system compares well with a laboratory system.
- **Precision:** This study shows the intermediate precision and repeatability of less than 5%.
- **Traceability of glucose monitoring system:** The results of Prodigy glucose monitoring system were compared to parallel results obtained on YSI 2300, which is the manufacturer's standard measurement procedure. The study shows that the Prodigy glucose monitoring system correlated very well with manufacturer's reference method.
- **The device has certified to meet the following standards:**
  98/79/EC, IEC 60601-1, IEC 61010-1, IEC 60601-1-2, IEC61326, and ISO 15197

Prodigy

WARRANTY

The Prodigy Blood Glucose Monitoring System is warranted to be free of
defects in material and workmanship for a period of one (1) year from
the date of purchase. This warranty extends only to the original
purchaser and is not transferable.

For warranty assistance, please contact:

Diagnostic Devices Inc.
Technical Support
1-800-243-2636

Prodigy

EXPECTED TEST RESULTS

Time of day	Glucose range for people without diabetes (mg/dL) / (mmol/L)	Your target range (mg/dL) / (mmol/L)
Before breakfast	(70~105) / (3.9~5.8)	_____ (mg/dL) / (mmol/L)
Before lunch or dinner	(70~110) / (3.9~6.1)	_____ (mg/dL) / (mmol/L)
1 hour after meals	Less than (160) / (8.9)	_____ (mg/dL) / (mmol/L)
2 hours after meals	Less than (120) / (6.7)	_____ (mg/dL) / (mmol/L)
Between 2 and 4 AM	Greater than (70) / (3.9)	_____ (mg/dL) / (mmol/L)

Source: Krall, L P, and Beaser. R.S.: Joslin Diabetes Manual.
Philadelphia: Lea and Febiger (1989), 138.

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Prodigy

Symbols convey information essential for proper use

Symbol	Referent
②	Do not re-use
📖i	Consult operating instruction
☀	Keep away from sunlight
☂	Keep dry
🌡	Temperature limitation
⊻	Use by
∿	Date of manufacture
LOT	Batch code
REF	Catalogue number
SN	Serial number
CONTROL	Control